

County Issues Workgroup

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ITEM NO: _____ 1 _____ Version Date: July 30, 2001 Revision

ITEM TITLE: County Hybrid Entity Definition

Premise

A County government is a “hybrid entity” as defined under the HIPAA Privacy Rules.

Reasoning

Section 164.504 of the HIPAA Privacy Rules defines a hybrid entity as “... a single legal entity that is a covered entity and whose covered functions are not its primary functions.”

Although it would be fair to say that health care is one of the primary functions of a California county, it would not be correct to state that health care is a county’s single most primary function, or that health care is even the dominant function of the County. The application of the hybrid entity definition then, seems to be dependent on how the term “primary functions” is interpreted.

The preamble to the HIPAA Privacy Rule provides the following explanation to help clarify how the hybrid entity definition should be applied;

“The term ‘primary functions’ in the definition of ‘hybrid entity’ is not meant to operate with mathematical precision. Rather, we intend that a more common sense evaluation take place: is most of what the covered entity does related to its health care functions? If so, then the whole entity should be covered.”

In addition, the preamble states, “The health care component rules [which include the hybrid entity definition] are designed for the situation in which the health care functions of the legal entity are not its dominant mission.”

Regardless of how a County ultimately interprets the hybrid entity rules, it seems it would be in the County’s best interest to be classified as a hybrid entity, as opposed to a single covered entity, for the following reasons:

- 1) The preamble to the HIPAA Privacy Rules states;

“Because some part of the legal entity meets the definition of a health plan or other covered entity, the legal entity as a whole could be required to comply with the [HIPAA Privacy] rules below. However, in such a situation, it makes sense not to require the entire entity to comply with the requirements of the

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rules below, when most of its activities may have little or nothing to do with the provision of health care; ...”.

Based on this statement, it would seem that a covered entity is required to apply the HIPAA rules to the entire organization, if the organization is not classified as a hybrid entity.

- 2) Other than the hybrid entity definition, the HIPAA Rules include no other provisions that would allow a HIPAA covered entity to exempt portions of the organization from conforming to the HIPAA Rules.
- 3) Given the choice, it is believed that a County would prefer to apply the HIPAA rules to only the County’s health care components, rather than the entire County.

Conclusion: Since it appears the intent of the hybrid entity definition is to allow covered entities to exempt the non-health care components of the entity from complying with the HIPAA rules, provided the health care component of the covered entity is not the entity’s dominant mission, and it is believed that applying such an exemption is preferable to the alternative, each California County should be classified as a hybrid entity.

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IMPLICATIONS

As a hybrid entity a county will be responsible for ensuring the health care component(s) of the county comply with the applicable HIPAA rules. The covered entity, i.e. the county, also retains the responsibility for compliance and enforcement, ensuring the implementation of appropriate policies and procedures, and "... for designating [and documenting] the components that are part of one or more health care components of the covered entity ..." [164.504(c)(3)].

There do not seem to be any specific requirements on how a county chooses to identify or group its health care components. A county could therefore choose to classify all health care related parts of the county as a single health care component, or it could choose to define multiple health care components. Furthermore, if a health care related part of the county is part of a larger department, for example a Health and Welfare Department, a county could choose to divide the department for the purposes of health care component identification.

The "health care component" definition stipulates that other non-health care components of a hybrid entity that would be considered a business associate of the hybrid entity's health care components, if the two components were separate legal entities, is part of the entity's health care component to the extent that "... the activities involve the use or disclosure of protected health information ..." [164.504(a)]. Therefore, any internal business-associate-like components of a county's health care component would have to be treated as part of that health care component, and documented accordingly.

The privacy rules require a contract between a covered entity and each of its business associates [164.502(e)(2)]. By definition a business associate is someone other than a member of the covered entity's workforce, and so it does not appear one component of a covered entity would ever be considered a business associate of another component of the same covered entity.

Although the rules pertaining to a hybrid entity do state that, "A reference ... to a 'covered entity' refers to a health care component of the covered entity;" this clause only applies to subpart E of Part 164 of the Privacy Rules. The definition of a business associate appears in Part 160, and therefore the use of the term "covered entity" in the business associate definition is assumed to refer to the primary entity, rather than only the health care component.

Since one component of a covered entity is never considered a business associate of another component of the same entity, regardless of whether an entity is classified as a hybrid entity or a single covered entity, it does not appear a business associate contract would ever be required between various components of a covered entity. However, it

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might be prudent to implement an MOU between the two components.

Whether or not a county is classified as a hybrid entity or single entity also does not appear to change when the county must use the standard HIPAA transactions. The transaction rule states:

“Except as otherwise provided in this part, if a covered entity conducts with another covered entity (or within the same covered entity), using electronic media, a transaction for which the secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction.” [162.923(a)].

Although, as implied by the above statement, there are some exceptions, for example when a covered entity sends or receives a transaction to or from a clearinghouse, none of the exceptions are impacted by the application of the hybrid entity definition. It is therefore necessary for a county to use the standard transactions internally, as well as externally, whenever conducting the transaction electronically, unless the exchange qualifies as one of the exceptions.

If a county concluded through interpretation of the HIPAA rules that said county was not a hybrid entity, all current and future standards adopted under HIPAA must be evaluated to determine how they would impact each of the county’s component parts, including both health care components and non-health care components.

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ITEM CHRONOLOGY

Workgroup Draft: 03/19/2001 Workgroup Approved: 03/19/2001

Approved Revisions: 05/21/2001, 07/30/2001, _____

SUPPLEMENTAL MATERIALS

Links to supporting legal and content expert opinions.